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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/451,939	12/01/1999	NINGNING MIAO	CIBT-P02-044	9684

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EXAMINER
BRANNOCK, MICHAEL T

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 04/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/451,939	Miao, et al.
Examiner	**Art Unit**
Michael Brannock	1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Feb 3, 2003*.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-4, 7, 9, 13-15, 17-21, and 23-51* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims *1-4, 7, 9, 13-15, 17-21, and 23-51* are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Continued Prosecution Application

1. The request filed on 2/3/03 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) is acceptable and a CPA has been established. An action on the CPA follows.

2. Applicant is notified that the amendments put forth in Paper 21, 2/3/03, have been entered in full.

Sequence Compliance

3. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the following reasons:. The specification makes reference to specific polynucleotide and polypeptide sequences, see page 60, for example; these references must contain a sequence identifier of the form: SEQ ID NO: X. Appropriate correction is required.

Response to Amendment

4. Applicant has amended elected claims 1-12, 16 and 22 such that the elected invention is no longer being claimed. Thus, a new restriction requirement is now issued and Applicant's arguments, as they relate to the amended claims, will be held in abeyance until the election of invention is made.

Election/Restriction

5. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 17-21, 49-51, drawn to *in vitro* methods of promoting survival of neuronal cells, as the claims are directed to the administration of polypeptides or small molecule agonists and antagonists, classified in class 514, subclass 2.

II. Claims 17-21, 49-51, drawn to methods of treatment, as the claims are directed to *in vivo* administration of polypeptides or small molecule agonists or antagonists, classified in class 514, subclass 2.

III. Claims 13-15, and 28, drawn to antisense nucleic acids and gene therapy, classified in class 514, subclass 44.

IV. Claims 23-27, drawn to compositions comprising small molecule antagonists, classification dependent on the chemical identity of the antagonist.

V. Claims 1-4, 7, 9, 29-34, drawn to polypeptides, classified in class 530, subclass 350.

VI. Claims 35-48, drawn to nucleic acids, classified in class 536, subclass 23.5.

6. The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different products, restriction is deemed to be proper because these products appear to constitute patentably distinct inventions for the following reasons: Groups IV-VI are directed to products that are distinct both physically and functionally, and are not required one for the other, and are therefore patentably distinct. Further, the protein of Group V can be prepared by processes which are materially different from recombinant DNA expression of Group VI, such as by chemical synthesis, or by isolation and purification from natural sources. Additionally, the DNA of Group VI can be used other than to make the protein of Group V, such in the gene therapy or as a probe in nucleic acid hybridization assays. Although, the protein Group V can be used to identify the antagonist of Group IV, the protein could also be used in the method of treatment of Group II. Although, the DNA of Group VI can be used to produce the protein of Group V which can be used to identify the antagonist of Group IV, the DNA could also be used to as a diagnostic probe. The antagonist of Group IV and is distinct from the protein and from the DNA because the antagonist could be obtained from sources other than those employing the protein of Group V or the DNA of Group VI, such as from commercial vendors.

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: Groups I-III are directed to methods that are distinct both physically and functionally, and are not required one for the other. Group I requires *in vitro* methods of promoting survival of neuronal cells, which is not required by any of the other groups. Group II requires methods of administering to a patient polypeptides, which are not required by any of the other groups. Group III requires gene therapy, which is not required by any of the other groups.

The polypeptides of Group V are related to the methods of Groups I and II as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptides of Group V are patentably distinct from each of the methods of Groups I and II because the polypeptides of Group V can be used in ways that are materially and functionally different than each of the methods because, as discussed above, each of the methods of Groups I and II are materially and functionally distinct from the others. Furthermore, the polypeptides of Group V and the method of Groups III are patentably distinct because one is not required for the use of the other.

The of antagonist of Group IV and the methods of Groups I and II are related as product and process of use, and are patentably distinct because the antagonist of Group IV can be used in

ways that are materially and functionally different than each of the methods of Groups I and II because, as discussed above, each of the methods of I and II are materially and functionally distinct from the others. Furthermore, the antagonist of Group IV and the methods of Group III are patentably distinct because one is not required for the use of the other.

The polynucleotides of Group VI are related to the method of Group III as product and process of use. In the instant case the polynucleotides of Group VI are patentably distinct from each of the methods of Group III because the polynucleotides of Group VI can be used in ways that are materially and functionally different than each of the methods such as hybridization assays for diagnostic purposes. Furthermore, the polynucleotides of Group VI and the methods of Groups I and II are patentably distinct because one is not required for the use of the other.

Therefore, a search and examination of all the groups in one patent application would result in an undue burden, since the searches for the groups are not co-extensive, the classification is different, and the subject matter is divergent.

7. This application contains claims directed to products and claims to methods using those products, comprising the following patentably distinct species: Sonic hedgehog polypeptides, Indian hedgehog polypeptides, Desert hedgehog polypeptides, Sonic hedgehog polynucleotides, Desert hedgehog polynucleotides, Indian hedgehog polynucleotides, small organic antagonists other than Protein Kinase A inhibitors, and Protein Kinase A inhibitors.

The above identified species are materially and functionally distinct molecules, the use of one not being required for the use of any other. Further, a search of one of the product species or

to methods of administering one species could not be relied upon, solely, to provide art that is anticipatory or would render obvious any other. Restriction is therefore proper.

8. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added.

9. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

10. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

11. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any

amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Brannock, Ph.D., whose telephone number is (703) 306-5876. The examiner can normally be reached on Mondays through Fridays from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

MB

April 10, 2003

YVONNE EYLER, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600